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Amendment and Response Serial No.: 10/732,782

Confirmation No.: 6883 Filed: December 10, 2003

For: CHEMOPREVENTIVE AND THERAPEUTIC ASPECTS OF POLYPHENOLIC COMPOSITIONS AND

**ASSAYS** 

## **Amendments to the Claims**

This listing of claims replaces all prior versions, and listings, of claims in the aboveidentified application:

1. (withdrawn) A method of determining if cancer cells are resistant to an agent, the method comprising:

determining the p57/KIP2 level in the cancer cells prior to contact with the agent; contacting the cancer cells with the agent;

determining the p57/KIP2 level in the cancer cells after contact with the agent; and comparing the p57/KIP2 level in the cancer cells after contact with the agent to the p57/KIP2 level in the cancer cells prior to contact with the agent;

wherein an increase in the p57/KIP2 level in the cancer cells after contact with the agent compared to the p57/KIP2 level in the cancer cells prior to contact with the agent indicates the cancer cells are resistant to the agent.

- 2. (previously presented) The method of claim 10, wherein the cancer cell is an epithelial carcinoma cell line.
- 3. (previously presented) The method of claim 2, wherein the epithelial carcinoma cell line is selected from the group consisting of an oral squamous carcinoma cell line, a metastatic oral carcinoma cell line, and a breast epithelial carcinoma cell line.
- 4. (previously presented) The method of claim 10, wherein the cancer cells are derived from a human epithelial carcinoma.

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5. (original) The method of claim 4, wherein the human epithelial carcinoma is selected from the group consisting of an oral squamous carcinoma, a metastatic oral carcinoma, and a breast epithelial carcinoma.

- 6. (previously presented) The method of claim 10, wherein determining the p57/KIP2 level is by detecting the p57/KIP2 protein.
- 7. (withdrawn/previously presented) The method of claim 10, wherein determining the p57/KIP2 level is by detecting the mRNA encoding p57/KIP2.
- 8. (withdrawn) A method of determining if cancer cells are sensitive to an agent, the method comprising:

determining the p57/KIP2 level in the cancer cells prior to contact with the agent; contacting the cancer cells with the agent;

determining the p57/KIP2 level in the cancer cells after contact with the agent; and comparing the p57/KIP2 level in the cancer cells after contact with the agent to the p57/KIP2 level in the cancer cells prior to contact with the agent;

wherein no increase in the p57/KIP2 level in the cancer cells after contact with the agent compared to the p57/KIP2 levels in the cancer cells prior to contact with the agent indicates the cancer cells are sensitive to the agent.

9. (withdrawn) A method of identifying an agent effective for the treatment of a cancer, the method comprising;

determining the p57/KIP2 level in cancer cells prior to contacting with the agent; contacting the cancer cells with the agent;

determining the p57/KIP2 level in the cancer cells after contacting with the agent; and comparing the p57/KIP2 level in the cancer cells after contacting with the agent to the

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p57/KIP2 level in the cancer cells prior to contacting with the agent;

wherein no increase in the p57/KIP2 level in the cancer cells after contacting with the agent compared to the p57/KIP2 level in the cancer cells prior to contacting with the agent indicates the agent is effective for the treatment of a cancer.

10. (original) A method of determining the therapeutic effectiveness of an agent, the method comprising:

contacting normal cells with the agent;

determining the p57/KIP2 level in the normal cells after contacting with the agent; contacting cancer cells with the agent;

determining the p57/KIP2 level in the cancer cells after contacting with the agent; and comparing the p57/KIP2 level in the normal cells after contacting with the agent to the p57/KIP2 level in the cancer cells after contacting with the agent;

wherein a higher p57/KIP2 level in the normal cells compared to the p57/KIP2 level in the cancer cells indicates the agent is effective for the treatment of cancer.

- 11. (original) The method of claim 10, wherein the normal cells and cancer cells are cultured together.
- 12. (cancel)
- 13-16. (canceled)
- 17. (previously presented) The method of claim 10, wherein the cancer cells are selected from the group consisting of oral cancer, esophageal cancer, gastric cancer, colorectal cancer, prostate cancer, bladder cancer, skin cancer, and cervical cancer.

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18-24. (canceled)

- 25. (previously presented) The method of claim 10, wherein both the cancer cells and normal cells are of epithelial origin.
- 26. (previously presented) The method of claim 10, wherein both the cancer cells and normal cells are human cells.

27-32. (canceled)

33. (previously presented) The method of claim 10, wherein the normal cells are normal human primary epidermal keratinocytes or fibroblasts.

34-35. (canceled)

36. (new) A method of identifying an agent with an apoptotic effect on cancer cells and a protective effect on normal cells, the method comprising:

contacting normal cells with the agent;

determining the p57/KIP2 level in the normal cells after contacting with the agent; contacting cancer cells with the agent;

determining the p57/KIP2 level in the cancer cells after contacting with the agent; and comparing the p57/KIP2 level in the normal cells after contacting with the agent to the p57/KIP2 level in the cancer cells after contacting with the agent;

wherein an higher p57/KIP2 level in the normal cells compared to the p57/KIP2 level in the cancer cells indicates the agent has an apoptotic effect on cancer cells and a protective effect on normal cells.